

1. The Combined References do not Teach Each Claim Limitation

The references, taken individually or in combination, do not teach or suggests that a hot-melt adhesive having copolymer blocks comprising styrene, would provide desirable adhesive properties and pharmaceutical release properties. Further, there is no teaching or suggestion to apply such an adhesive mixture to a stitch-bonded nonwoven backing material as required in the amended claims.

The major thrust of Kantner's disclosure is use of hydrophilic PEG-based adhesives. See Abstract; col 4, line 15 et seq. A key rationale provided for the hydrophilic PEG adhesives is that it may be easily plasticized by the addition of other non-volatile polar solvents. Col. 2, lines 25-50.

In addition, Kantner discloses that an additional desirable property of his adhesive is that it will retain moisture so as to prevent cracking due to drying/evaporation. Col. 2, lines 35-40. Prevention of drying is a key issue as this underlies Kantner's strong preference on non-volatile solvents. In fact, Kantner explicitly refers to his hydrophilic adhesive as *swellable*. Col. 2, lines 67 to col. 3. Therefore, Kantner conceived of the adhesive as having substantial water/solvent retention properties.

The combination of Kantner with Riedel does not render the claims obvious because Examiner's proposed modification does not provide for each limitation in claim 1. Neither reference discloses the use of a hot-melt adhesive having styrene-containing block copolymers. The adhesive recited in claim 1 would be hydrophobic and dry – solvent free after drying – which is very different in chemical structure from Kantner's.

The differences in chemical formulation (i.e., PEG vs. styrene-containing copolymers), the adhesive's hydrophobicity/electrophilicity and degree of hydration +/- solvation indicate substantial differences. Under these circumstances the PTO guidelines instruct that examiners may not presume that the two adhesives have similar properties and, that the tapes would also be expected to behave similarly. MPEP § 2144.09. In other words, the differences in the adhesives do not make out a *prima facie* case of obviousness.

It is respectfully suggested that the rejections may be properly withdrawn on this basis alone.

**2. There Would be Insufficient Motivation to Combine the Kantner and Riedel.**

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. MPEP § 2143, citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). In order to find such motivation or suggestion there should be a reasonable likelihood that the claimed invention would have the properties disclosed by the prior art teachings.

Kantner's disclosure is completely dedicated to hydrophilic PEG-based adhesives; admixture of the adhesive with antimicrobials and other agents is also referred to. There is no teaching or suggestion that the antimicrobials and other pharmaceutical agents would exhibit their effective properties if used with different adhesives; especially adhesives having very different composition and properties as does Applicants'.

The rejection is predicated on Examiner combining Kantner's adhesive/drug mixture with Riedel's backing. Final Action, p. 3, 1st ¶. However, this combination does not overcome the motivational-gap caused by the distinct structure and properties of Kantner's adhesive/drug composition. Thus, following *Vaeck*, it is Applicants' position that the rejection is not sufficiently inferred by the combined references to sustain the rejection.

Withdrawal of the rejection is respectfully requested.

**3. The Asserted References do not Provide an Enabling Disclosure**

The "test" for enablement for the asserted references, is whether they describe all sources and methodology in such detail that a person of ordinary skill in the art could reproduce the results reported therein. *In re Hoeksema*, 158 USPQ 596, 601 (CCPA 1968), (wherein the Court stated "While *In re Le Grice* was bottomed on an issue arising under 35 U.S.C. 102 where the reference was a 'printed publication,' that test, in our view, is also properly applicable to issues arising under 35 U.S.C. 103.")


A reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the date of invention. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985). See MPEP § 2121.01.

Applicants suggest that neither Kantner nor Riedel, individually or in combination, provide sufficient guidance to arrive that the invention of claim 1. Specifically, there is no teaching or suggestion as to how to vary the many experimental variables needed to achieve the proper balance for strong adhesion while maintaining the desired release properties.

Viewed in this light, Kantner and Riedel provide a nonenabling disclosure that rises, at best, to the level of *obvious to try*, i.e., they provide an invitation to experiment. However, this is insufficient to maintain the rejection because the combination of references fails to provide a reasonable expectation of success. See e.g., MPEP §§ 2143.02, 2144.06.

In view of these remarks and the foregoing amendments, withdrawal of the rejections under § 103(a) is respectfully requested.

Respectfully submitted,  
NORRIS, MCLAUGHLIN & MARCUS

  
Theodore A. Gottlieb, PhD  
(Reg. No. 42,597)  
220 East 42<sup>nd</sup> Street  
New York, NY 10017  
telephone (646) 487-5675  
facsimile (212) 808-0844